

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 08 JUN 2004

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Applicant's or agent's file reference P35024WO/NJL	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/00064	International filing date (day/month/year) 10.01.2003	Priority date (day/month/year) 11.01.2002
International Patent Classification (IPC) or both national classification and IPC C12Q1/68		
Applicant UNIVERSITY OF SOUTHAMPTON et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 17.07.2003	Date of completion of this report 07.06.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Brochado Garganta, M Telephone No. +49 89 2399-8935 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/00064**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*

Description, Pages

1-20 as originally filed

Claims, Numbers

1-21 received on 26.03.2004 with letter of 26.03.2004

Drawings, Sheets

1/7-7/7 as originally filed

Sequence listing part of the description, pages:

1-3, filed with the letter of 28.03.03,

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☒ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,6-8,11,13-15,18-20
	No: Claims	1-3,5,9-10,12,16,17,21
Inventive step (IS)	Yes: Claims	4,6-8,11,13-15,18-20
	No: Claims	1-3,5,9-10,12,16,17,21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

(D1) WO 0146469 A

(D2) US 5851759 A

(D3) BUKH J ET AL: 'SEQUENCE ANALYSIS OF THE 5' NONCODING REGION OF HEPATITIS C VIRUS' PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, vol. 89, no. 11, 1 June 1992 (1992-06-01), pages 4942-4946, XP000384404 ISSN: 0027-8424

2. The amendments filed on 26.03.04 do not introduce additional subject-matter, which extends beyond the content of the application as filed. Therefore, the amendments meet the requirements of Article 34(2)(b) PCT.

3. Novelty

- 3.1 The subject-matter of claim 1, relating to a method of differentiating HCV genotype 1 (HCV-1) from HCV genotypes 2 and 3 (HCV-2 and HCV-3) in a sample, is not new in the sense of Article 33(2) PCT, because a method with the claimed features is already known from D1 and D2.

D1 discloses a method of judging hepatitis C virus genotype 1, wherein primers capable of specifically hybridising to the 5' non-coding region (5' NCR) of HCV are used for amplifying this region by PCR (see abstract).

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D2 discloses primers and methods for the characterisation of HCV genotyping, wherein primers are used which anneal to the 5' NCR for amplifying a fragment of the HCV-1 genome, said amplification being a PCR (see columns 1 and 2).

The additional features of claims 2-3, 5, 9-10 and 12, the features of claims 16 and 17, relating to a kit, and of claim 21 relating to a method, are all known from D2 (see columns 1, 2, and 8-12), and therefore these claims are not novel (Article 33(2) PCT).

3.2 Claims 4, 6-8, 11, 13-15 and 18-20 are considered to be novel (Article 33(2) PCT), as the sequences indicated are not disclosed as such in the prior art.

4. Inventive step

D3 discloses the sequence of the 5' NCR of the HCV, wherein a significantly greater sequence heterogeneity than reported before was found. Highly conserved domains are indicated (see pages 4942, 4945 and 4946 and figure 1).

Knowing the sequence of the 5' NCR of the HCV, it cannot be said that the person skilled would select the given oligonucleotides for the amplification of the 5' NCR, or hybridising to it, as D3 does not teach that there is a part of the 5'NCR which can differentiate HCV-1 from the other genotypes.

Thus, claims 4, 6-8, 11, 13-15 and 18-20 seem to be based on an inventive step (Article 33(3) PCT).